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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,367	10/24/2003	Audrey Minden	0575/55311-AZ-PCT-US/JPW/	2322

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COOPER & DUNHAM, LLP
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,367	MINDEN, AUDREY	
	Examiner	Art Unit	
	MICHAEL SZPERKA	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65,67,72 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65,67,72 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2007 has been entered.

Applicant's response and amendments received November 5, 2007 are acknowledged.

Claims 1-64, 66, and 68-71 have been canceled.
Claim 65 has been amended.
Claims 72 and 73 have been added.
Claims 65, 67, 72 and 73 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 65 and 67 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the recitation of new matter has been withdrawn in view of applicant's amendments to the claims which removed the new matter from the claimed invention.

4. Applicant's response and amendments received November 5, 2007 have overcome all prior grounds of rejections. However, these amendments have introduced the following new issues discussed below.

5. Claims 65, 67, 72, and 73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies that bind an epitope of SEQ ID NO:2 and block the interaction of the human PAK4 serine/threonine kinase of SEQ ID NO:2 with GTP binding proteins, said interaction between PAK4 and GTP binding proteins occurring at the GTP binding domain of human PAK4 which consists of SEQ ID NO:6, does not reasonably provide enablement for antibodies that generically bind to human PAK4 serine/threonine kinases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification discloses the identification of the full length sequence of a human serine/threonine kinase designated PAK4 whose sequence consists of SEQ ID NO:2. The specification also discloses that PAK4 interacts with GTP binding proteins, such as Cdc42Hs and Rac via the epitope of SEQ ID NO:6 disclosed in figure 1D. Note that SEQ ID NO:6 is a subsequence of SEQ ID NO:2. It is further disclosed that antibodies can be made that block the interaction between PAK4 and GTP binding proteins. However, the specification does not appear to define the term "human PAK4 serine/threonine kinase" as being limited to a polypeptide consisting of SEQ ID NO:2, and indeed it is disclosed that altered forms, such a truncations, mutations and other derivatives which differ in sequence from SEQ ID NO:2 are contemplated as part of the instant invention (see particularly pages 13-15 of the instant specification). Further, Plowman et al. (of record) disclose a polypeptide identified as human PAK4 that differs markedly from SEQ ID NO:2 of the instant invention. As such, the genus of PAK4 protein sequences is quite large and therefore the genus of antibodies that bind to PAK4 polypeptides is larger still. It is known in the art that antibody binding to related sequences can be unpredictable, with even a single amino acid substitution potentially eliminating antibody binding to an antigen (Colman, P.M., Research in Immunology,

1994, 145:33-36, see entire document, particularly the third sentence of the right column of page 33). As such, antibodies that bind to PAK4 kinases need not bind SEQ ID NO:2, nor would antibodies that bind SEQ ID NO:2 necessarily bind all PAK4 kinases. While it is routine in the art to make an antibody that binds any given sequence, all of the disclosed uses for antibodies appear to be predicated on their ability to bind the PAK4 kinase of SEQ ID NO:2 and therefore it is unclear how a skilled artisan would use the breadth of the instant claimed antibodies.

Therefore, based upon the guidance and direction of the specification, the statements of the prior art, and the unpredictability of biological systems, a skilled artisan would be unable to make and use the breadth of applicant's claimed antibodies without conducting additional, unpredictable research.

6. Claims 65, 67, 72, and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant has broadly claimed antibodies that bind human PAK4 kinases. The specification discloses the specific human PAK4 sequence of SEQ ID NO:2 and indicates that fragments and mutated forms are also contemplated as part of the invention. Note that the specification discloses that the domain of SEQ ID NO:2 that is responsible for interactions with GTP binding proteins such as Cdc42Hs and Rac is the domain consisting of SEQ ID NO:6 (see particularly Figure 1D of the specification). The PAK4 kinases recited in the instant claims are not recited as having any activity other than that they bind GTP binding proteins such that this activity can be blocked by the claimed genus of antibodies.

The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of

relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Fri. January 5, 2001, see especially page 1106 column 3).

In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412) 19 F. 3d 1559, the court noted: "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

The court has further stated that "Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

As discussed above, the only recited function for the recited genus of PAK4 molecules in that they bind GTP binding proteins. Note that the claims recite that the interaction between PAK4 and a GTP binding protein takes place at a domain "comprising consecutive amino acids having a sequence as set forth in SEQ ID NO:6". The claim recites "a sequence" rather than "the sequence" and as such its broadest reasonable interpretation is that the recited PAK4 need not comprise the entirety of the

21 amino acids of SEQ ID NO:6. The phrase "consecutive" reasonably means that the recited PAK4 must minimally comprise 2 consecutive amino acids of SEQ ID NO:6. As such, the required recited structure does not appear to be correlated with the function of binding to molecules such as Cdc42Hs and Rac. As such, while applicant is clearly in possession of the polypeptide of SEQ ID NO:2, applicant does not appear to be in the possession of all human PAK4 sequences. Consequently, applicant cannot reasonably be said to be in possession of the genus of antibodies binding a genus of polypeptides that were not possessed.

Therefore, a skilled artisan at the time the invention was made would reasonably conclude that while applicant was in possession of antibodies that bind epitopes within SEQ ID NO:2 and block the binding of SEQ ID NO:2 to GTP binding proteins, said binding between SEQ ID NO:2 and GTP binding proteins occurring at the PAK4 epitope of SEQ ID NO:6, applicant was not in possession of the broader genus of antibodies that bind all human PAK4 kinases.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL SZPERKA whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Primary Examiner
Art Unit 1644

/Michael Szperka, Ph.D./
Primary Examiner, Art Unit 1644